TEXT OF FINAL REGULATIONS

Proposed deletions are indicated by ~~strikeout~~.
Proposed additions are indicated by underline.

TITLE 3. CALIFORNIA CODE OF REGULATIONS
DIVISION 6. PESTICIDES AND PEST CONTROL OPERATIONS
CHAPTER 1. PESTICIDE REGULATORY PROGRAM
SUBCHAPTER 1. DEFINITION OF TERMS
ARTICLE 1. DEFINITIONS FOR DIVISION 6

Amend section 6000 by adding, in alphabetical order, the following definitions:

6000. Definitions.

. . . .

"Human Participant" means a living person who participates in a human pesticide exposure study conducted in order to obtain (1) data through intervention or interaction with the participant, or (2) identifiable private information. Intervention, as used in this definition, includes both physical procedures by which data are gathered and manipulations of the participant or the participant's environment that are performed for research purposes. Interaction, as used in this definition, includes communication or interpersonal contact between the investigator and human participant. Private information, as used in this definition, includes information about behavior that occurs in a context in which a participant can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by a participant and which the participant can reasonably expect will not be made public. Private information must be individually identifiable in order for the acquisition of that information to constitute research involving human participants. Individually identifiable means that the identity of the participant is or may readily be ascertained by the investigator or associated with the information.

"Institutional Review Board (IRB)" means an objective committee whose purpose is to review protocols of human pesticide exposure studies to ensure the safety and general welfare of the human participants, and to guarantee that their human rights are not violated. The Institutional Review Board shall meet the requirements as specified in Title 40 Code of Federal Regulations, (Protection of Environment), Part 26, (Protection of Human Subjects), when conducting a review of a protocol.

"Pesticide exposure study" means:

(a) A data gathering project that meets one or more of the following criteria:

(1) Human participants are to be directly exposed to the pesticide for the purpose of determining its pharmacokinetics or pharmacodynamics;

(2) Human participants are monitored and the use of the pesticide is not consistent with current accepted labeling or current regulations;

(3) Humans are exposed as the result of a contrived application in order to monitor exposure without routine pest control being a significant objective;

(4) Human participants are monitored for the purpose of satisfying initial or continuing registration requirements of the U.S. Environmental Protection Agency or the department; or

(5) Human participants are monitored to develop or contribute knowledge of pesticide exposure to be generalized to other populations.

(b) "Pesticide exposure study" does not include the following:

(1) Data collected for the purpose of satisfying an existing health standard for exposure monitoring or if it is understood that routine monitoring is a condition of employment;

(2) Unscheduled monitoring of persons in response to a medical emergency to identify possible sources of exposure;

(3) Monitoring conducted by a government agency or by an employer, to determine the workplace exposure of his or her employees.

(4) Monitoring requested by an individual or group of individuals to determine personal exposure levels.

(5) The analysis or evaluation, after the human participant involvement has ceased, of existing or previously collected data, documents, records, specimens, or samples, if these sources are publicly available or if the information is recorded by the study director in such a manner that the human participants cannot be identified, directly or through identifiers linked to the participants.

"Study director" means the individual responsible for the overall conduct of a research project.

. . . .

NOTE: Authority cited: Sections 11456, 11502, 12111, 12781, 12976, 12981, and 14005, Food and Agricultural Code. Reference: Sections 11408, 11410, 11501, 11701, 11702(b), 11704, 11708(a), 12042(f), 12103, 12971, 12972, 12973, 12980, 12981, 13145, 13146, and 14006, Food and Agricultural Code.

CHAPTER 3. PEST CONTROL OPERATIONS
SUBCHAPTER 3. PESTICIDE WORKER SAFETY
ARTICLE 1. GENERAL SCOPE AND PURPOSE

Repeal section 6710:

6710. Studies on Pesticide Safety.

(a) No person shall conduct any pesticide exposure study in California, which involves human participants, except as provided in subsection (g), unless the Director has given written approval of the protocol. The study shall be conducted in accordance with the approved protocol. The protocol shall be submitted to the department, in writing, and shall be no more than ten double-spaced pages, exclusive of appendices. The protocol shall include the following, addressed in the order given below:

(1) A descriptive title and statement of the aim/purpose of the study, including:

(A) Identification of the test and control substance by name, chemical abstract (CAS) number or code number;

(B) A statement as to whether the test substance is a currently registered pesticide;

(C) A statement as to whether the pesticide will be used in accordance with labeling directions and applied at the maximum rates listed on the labeling, if a currently registered pesticide is to be used. Provide an explanation if the pesticide is to be applied other an in accordance with labeling directions and/or at less than the maximum labeling rate; and

(D) The proposed starting and completion dates, including the date of submission of the final report;

(2) Background for the study, including previous relevant research and justification for the participation of humans in the study;

(3) The significance of the study;

(4) Methods to be used in conducting the study, including a description of:

(A) The study design, including type and frequency of tests, measurements to be made and methods for the control of bias;

(B) The methods of data analysis;

(C) How the human participants will be selected, including:

1.Who the proposed human participants are, including whether or not they usually handle or are exposed to pesticides;

2.A justification for studying this group of individuals;

3.The total number of humans participating in the study and rationale for using that number of participants;

4.Criteria, including medical conditions, used for exclusion or inclusion of human participants;

(D) How the human participants will be recruited, including:

1.Detail the source(s) of prospective human participants;

2.Describe how and by whom human participants will be contacted initially;

(E) How, when, and by whom written consent will be obtained from the participants. The consent form must be written in a language understandable to the participant and accompanied by a Research Participant Bill of Rights. An example of a consent

~~document and a copy of the Bill of Rights can be found in Health and Safety Report 1619 (HS-1619), available from the department.~~

~~(F) Study procedures, including:~~

~~1. The frequency and duration of each study procedure; and~~

~~2. The location(s) where the study procedures will be carried out;~~

~~(G) Possible risks and discomforts to human participants, a discussion of the significance of the risks and descriptions of how the risks were assessed, and an explanation of how the participants will be informed of the potential risks;~~

~~(H) How participants will be provided any necessary medical care or medical supervision and a statement of who is to bear the cost of such care;~~

~~(I) How human participants will be informed that their participation in the study is voluntary and that they may leave the study at any time with no penalty;~~

~~(J) Any costs that the human participant or a third party (e.g. insurance) may be expected to assume;~~

~~(K) How human participants are to be paid for their participation in the study beyond their normal salary, including a description of the type and amount of payment to be offered; and~~

~~(L) Whether the research records will be anonymous. If not, include a discussion of how the records will be kept and where and how signed consent forms will be maintained;~~

~~(5) A brief list of the qualifications of investigators;~~

~~(6) A reference for all attachments;~~

~~(7) A bibliography; and~~

~~(8) The signature of the study director and/or principal investigator.~~

~~(b) Protocols submitted to the Director for review shall be submitted to the Office of Environmental Health Hazard Assessment (OEHHA) for its concurrent review.~~

~~(c) The department shall submit the protocol to an appropriate committee of a public or private California research university, which has an agreement with the department to review protocols with regard to use of human participants in research. After review of the protocol, the committee shall make a recommendation to the Director regarding approval of the protocol. The Director shall make the final decision and inform the registrant of the decision.~~

~~(d) Protocol sponsors shall be required to pay $300 per protocol to cover the costs incurred by the committee referred to in subsection (c) in reviewing the protocol.~~

~~(e) Approval of a study protocol is valid for one year. Before the end of that year, the person conducting the study must submit a final report or request, in writing, that the approval be reviewed for renewal. Upon request for renewal, the study may continue pending review by the Director.~~

~~(f) Once approved, no changes may be made to the study protocol without the approval of the Director. Requests to amend the protocol must be submitted in writing (except as provided below), and the written approval of the Director must be received prior to implementing the proposed change. If the change to the study protocol will have an impact on the human participants, the changes must also be approved by the committee referred to in subsection (c). The Director may accept changes conveyed orally and give oral approval for changes to the protocol that he or she determines to be minor, and to have no impact on the human participants in the study. When an oral request is made and~~

~~oral approval is given, written notice of the change must be submitted to the department within 24 hours.~~

~~(g) The following exemptions apply to this section:~~

~~(1) Studies which have been approved by a human subjects review committee of any university or medical institution in California are exempt from the approval process described in subsection (c).~~

~~(2) Studies conducted by any university or medical institution in California which are conducted only for the purpose of research and are not intended for submission to the department or the U.S. EPA to support the registration of a pesticide are exempt from the requirements of this section.~~

~~(h) The director, agricultural commissioner of the county where the study is taking place, or the chair (or a representative) of the committee referred to in subsection (c), may order any human exposure in the study to cease immediately, and the director may cancel approval of the study whenever it is deemed necessary to protect employee safety, public safety, or the environment.~~

~~NOTE: Authority cited: Sections 12976 and 12981, Food and Agricultural Code. Reference: Sections 12980, 12981, 12987 and 12988, Food and Agricultural Code~~.

Adopt section 6710 to read:

6710. Pesticide Exposure Studies Involving Human Participants.

(a) No person shall conduct any pesticide exposure study in California, which involves human participants, unless the Director has given written authorization to the study director to conduct the pesticide exposure study according to an approved protocol.

(b) The study director shall submit the protocol to the Director for review and provisionary determination of acceptability.

(c) The Director shall forward a copy of the protocol and review documentation to the Office of Environmental Health Hazard Assessment for concurrent review.

(d) The Director shall provide comments to the study director on the basis of Department of Pesticide Regulation review and any comments from the Office of Environmental Health Hazard Assessment. The study director shall make any changes deemed necessary by the Director. Upon receipt of the Director's provisionary determination of acceptability, the study director shall obtain a review and approval from an Institutional Review Board (IRB). The IRB must conduct its review in compliance with Title 40 Code of Federal Regulations (Protection of Environment), Part 26 (Protection of Human Subjects).

(e) The study director shall submit to the Director the IRB's approval of the protocol and all documentation exchanged between the IRB and the study director related to the review.

(f) The Director shall make the final decision regarding approval or denial of the protocol based on the information required in subsection (e), other relevant available information available to the Director. The Director shall notify the study director in writing of the decision and the basis for the decision.

(g) The Director shall establish an expiration date for the approved protocol. In no instances shall the expiration date exceed that established by the IRB. If a pesticide exposure study is not completed by the expiration date established by the Director, the study director shall not continue the pesticide exposure study until the Director has approved the renewal of the protocol in writing as required in subsection (i).

(h) Protocol Amendment. The study director shall not make an amendment to the approved protocol that may impact the health of the human participants without approval from the Director. For amendments where participant health is potentially impacted, the study director shall make the request in writing. The proposed amendment, justification, potential impact on study participants, and any measures proposed to mitigate potential impacts shall accompany the request. The Director shall forward a copy of the proposed amendment and any accompanying documentation to the Office of Environmental Health Hazard Assessment for concurrent review. The Director shall provide comments to the study director on the basis of Department of Pesticide Regulation review and any comments from the Office of Environmental Health Hazard Assessment. The study director shall make any changes deemed necessary by the Director. Upon receipt of the Director's provisionary determination of acceptability, the study director shall obtain a review and approval of the proposed amendment from an IRB as required in subsection (d). The study director shall submit to the Director the protocol and all documentation exchanged between the IRB and the study director. The Director shall notify the study director of the decision and the basis for the decision. If approved by the Director, the pesticide exposure study shall be conducted in accordance with the approved amended protocol. In the event that the potential impact on human participants is uncertain, the study director shall consult with the Director.

(i) Renewal of Protocol. The study director shall obtain approval of renewal from an IRB as described in subsection (d) prior to requesting the Director’s approval to renew the protocol. The study director shall submit, to the Director, the protocol and all documentation exchanged between the IRB and the study director regarding the renewal. After reviewing the documentation, if the Director approves the request for protocol renewal, the Director shall establish a revised expiration date. The revised expiration shall not exceed that date established in the IRB's renewal recommendation.

(j) In the event of any complications or adverse health effects identified during the conduct of the study, the study director shall take immediate action to ensure the health and safety of the human participants. The study director shall immediately notify the Director of such complications or adverse health effects and the immediate actions taken.

(k) The study director shall submit the following information to the Director by the expiration date:

(1) A statement regarding the status of the study including information as to whether the study was completed, postponed, or cancelled.

(2) A report and explanation of any complications or adverse health effects involving the human participants and what actions were taken.

(l) The Director or agricultural commissioner of the county where the study is taking place may inspect the pesticide exposure study activities to evaluate compliance with the protocol. The Director or commissioner may order the study director or human participants to cease immediately any human pesticide exposure activity conducted during the study to protect the safety of the human participants. The Director may cancel

the authorization to conduct the pesticide exposure study whenever it is deemed necessary to protect participant safety, public safety, or the environment.

NOTE: Authority cited: Sections 12976 and 12981, Food and Agricultural Code. Reference: Sections 12980, 12981, 12987 and 12988, Food and Agricultural Code.